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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,223	07/11/2003	Eric K. Mangiardi	000100.0015	4411
37305	7590	10/14/2005	EXAMINER	
ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET SUITE 4000 CHARLOTTE, NC 28280-4000			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,223

Applicant(s)

MANGIARDI ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-24,37 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-24,37 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09062005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed August 3, 2005. The Examiner acknowledges the amendments to the specification; the amendments to claims 1, 3, 5-7, 10, 12, 13, 15, 17, 20, 24, 37, 39, 41 and 42; and the cancellation of claims 2, 9, 25-36 and 38. Claims 1, 3-8, 10-24, 37 and 39-42 are pending.

Drawings

2. The drawings remain objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "100" as mentioned at page 8, lines 15 and 16, and page 9, line 25. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 6, 13 and 42 are objected to because of the following informalities: at lines 3-4 of each claim, "a first and second locations" apparently should read either --first and second locations-- or --a first and second location--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 3, 6-8, 10, 13, 37, 39 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Matthews et al. ('351). Matthews et al. teach a measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (110) includes an exterior conduit (120) having measurement markers (152) formed on a portion thereof; an interior conduit (130) slidably disposed within the exterior conduit and having a depth marking mechanism (132) which may be visible through a portion of the exterior conduit (col. 6, lines 9-11); a measurement assembly including a plurality (two) of legs (140, 142) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (136, 138, 139) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration. The inward facing surfaces along a portion of the legs are substantially flush with

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one another when the measurement assembly is closed. The legs form an acute angle (150) with respect to one another as the measurement assembly is moved distally in relation to the first conduit. The handle further includes a measurement indicator (edge of opening (134), wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen in the knee of a patient so as to select a suitable interventional prosthesis. In operations the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length of the target segment is measured within the patient. An optical scope may be operatively coupled therewith (col. 3, lines 21-23), so that the measuring step may be accomplished using the optical scope.

6. Claims 1, 3, 4, 6-8, 10, 11, 13-23, 37, 39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Colvin et al. ('892). Colvin et al. teach a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (12) having measurement markers (24) formed on a portion thereof; an interior conduit (16) slidably disposed within the exterior conduit and having a depth marking mechanism (22) which may be visible through a portion of the exterior conduit (20); a measurement assembly including a plurality of legs (54a-54c) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (14) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly (18) by actuating the handle along a

continuum between a first closed configuration and a second open configuration. The inward facing surfaces along a portion of the legs are substantially flush with one another when the measurement assembly is closed. The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit. The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations. The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. In operations the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the length of the target segment is measured within the patient. An optical endoscope may be operatively coupled therewith, so that the measuring step may be accomplished using the optical endoscope. The device may be used to measure the diameter and length of a stenotic target segment of the lumen within the patient, including the height and length of the stenosis.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 5, 12, 24, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colvin et al. ('892) in view of Jain ('147).

Regarding claims 24 and 40, Colvin et al., as discussed above, teach all of the limitations of the claims except that the measurement assembly includes four legs. Jain teaches a vessel measuring device including an exterior conduit (22), an interior conduit (24), and a measurement

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assembly including four or more legs (44, see Figure 3). Applicant has not disclosed that using a measurement assembly having four legs solves any stated problem or is for any particular purpose. Moreover, it appears that the measurement assembly of Colvin et al. would perform equally well with the four legs, rather than two or three legs. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Colvin et al., to include a measurement assembly having four or more legs, similar to that of Jain, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Colvin et al.

Regarding claims 5, 12 and 41, Colvin et al., as discussed above, teach all of the limitations of the claims except that the distal ends of the legs are coupled together and the measurement of the target site takes place between the distal and proximal ends of the legs. Jain teaches an alternate embodiment of the distal end of a vessel measuring device including an exterior conduit (22), an interior conduit (24), and a measurement assembly (54) including at least two legs (56,58) where the measurement of the target site takes place between the distal and proximal ends of the legs (see Figures 5 and 6). Applicant has not disclosed that using a measurement assembly having at least two legs where the distal ends of the legs are coupled together and the measurement of the target site takes place between the distal and proximal ends of the legs solves any stated problem or is for any particular purpose. Moreover, it appears that the measurement assembly of Colvin et al. would perform equally well with a measurement assembly similar to the second embodiment of Jain having at least two legs where the distal ends of the legs are coupled together. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Colvin et al., to

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include a measurement assembly having at least two legs where the distal ends of the legs are coupled together, similar to that of Jain, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Colvin et al.

Response to Arguments

9. Applicant's arguments filed August 3, 2005 have been fully considered but they are not persuasive.

Applicant contends that Matthews, Colvin, and Jain, alone or in combination, fail to teach or suggest a measurement assembly having legs with distal ends having inward facing surfaces configured to be substantially flush in a closed position, as recited in independent Claims 1, 7, 24 and 37. Applicant asserts that the wire of Matthews must deploy through a flared tip in order to measure a lumen, and therefore cannot be said to constrain the wires substantially flush against each other. Applicant argues that the rounded balls at the ends of each of the bifurcated portions of Colvin prevent the portions from lying substantially flush against each other. Applicant finally contends that arms of the measurement assembly of Jain have a significant gap between the arms even when in the "longitudinally flat position. These arguments are not persuasive.

First, the Examiner respectfully submits that contrary to Applicant's argument that no prior art of record disclose a measurement assembly having legs with *distal ends having* inward facing surfaces configured to be substantially flush in a closed position as allegedly recited in the independent claims, the claim language of the independent claims only requires that inward facing surfaces of the legs are substantially flush with each other in the closed position. More specifically, the claim language does not specify what portion of the inward facing surfaces are

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substantially flush with each other in the closed position. The claims do not limit the flush arrangement to be at the distal ends of the legs or along the entirety of the inward facing surfaces. Therefore, at least the inward facing portions of the proximal ends of the legs in the measurement assemblies of Matthews, Colvin and Jain can all be said to be substantially flush with each other in the closed configuration.

Second, the Examiner respectfully submits that Applicant has failed to show criticality of this feature of the claimed invention. The original disclosure of the present application fails to state any particular problem that a substantially flush arrangement of the inward facing surfaces of the measurement assembly legs in a closed configuration is intended to solve. The original disclosure is also silent with respect to any advantages of such a configuration. In the Remarks filed August 3, 2005, at the last sentence on page 11, Applicant alleges that advantageously, the ability of the legs to lie substantially flush at their distal ends allows the distal end of the legs to pass through a narrowed portion of a lumen, such as past a blockage, to measure the lumen on the other side of the narrowed portion. The Examiner respectfully disagrees. According to the disclosure of the instant application, the closed configuration is when the measurement assembly is fully disposed within the exterior conduit. When the measurement assembly is moved to the open configuration, the moment the distal end of the measurement assembly passes the distal end of the exterior conduit there is no disclosure that inward facing surfaces of the legs remain substantially flush with one another, and this appears not to be the case. Therefore, it appears to be the closed configuration within the exterior conduit, and more particularly the diameter of the exterior conduit itself, that allows the distal end of the legs to pass through a narrowed portion of a lumen, such as past a blockage, to measure the lumen on the other side of the narrowed portion

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contrary to Applicant's assertion. The Examiner respectfully submits that each of Matthews, Colvin and Jain teach a closed configuration of each apparatus where the measurement assembly is fully disposed within the exterior conduit, where each apparatus appears equally capable of allowing the distal end of the legs of the respective measurement assemblies to pass through a narrowed portion of a lumen, such as past a blockage, to measure the lumen on the other side of the narrowed portion as the present invention. Moreover, the Examiner respectfully submits that should an operator select an exterior conduit of sufficiently small diameter for use in the respective apparatus of each of Matthews, Colvin and Jain, the inward facing surfaces of the legs of the measurement assemblies of each apparatus would be capable of being compressed to the extent that they are substantially flush with each other along the lengths thereof.

Finally, the Examiner respectfully submits that *The American Heritage® Dictionary of the English Language, Fourth Edition* (©2000) defines the adjective "flush" to mean "[5.b.] Arranged with adjacent sides, surfaces, or edges close together: *a sofa flush against the wall.*" In view of this definition of the term flush, the inward facing surfaces of the legs of each of the measurement assemblies of Matthews, Colvin and Jain can be said to be *substantially flush* in the closed configuration, as they are arranged close together irregardless of whether or not some gap exists between the inward facing surfaces.

In view of the foregoing, the rejections citing at least one of Matthews, Colvin and Jain have been maintained.

Applicant's arguments with respect to the rejection of claims 1, 5-7, 12-14, 16-23, 37, 41 and 42 under 35 U.S.C. 102(e) as being anticipated by Korotko et al. have been considered and are not fully persuasive. However, this rejection has been withdrawn because the inner surfaces

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of the legs (130) of the measurement assembly are separated by a separate central lumen (138).

In view of the foregoing, it is arguable whether the inner surfaces of the legs may be considered substantially flush when the measurement assembly is closed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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October 6, 2005